

### **DETAILED ACTION**

1. Appeal brief filed 6/21/11 is acknowledged. Finality of the previous Office Action of 9/14/2010 is withdrawn. Claims 1-3 and 5-8 are examined.

2. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response and withdrawn.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3a. Claims 1-3 and 5-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process for the recovery chemokine of SEQ ID NO: 1, does not reasonably provide enablement for recovering all chemokine molecules expressed in prokaryotic host cells as inclusion bodies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The breadth of the claims is excessive because the claims read on any chemokine recovery.

While the specification provides guidance and examples showing recovery of chemokine of SEQ ID NO: 1 [page 10]. There is no guidance or examples to teach the recovery of the other chemokines. A person of ordinary skill in the art would know that chemokines encompass a wide range of proteins. In addition, the specification does not

disclose all chemokines recovered by the instant method of interposing a Reverse Phase Chromatography step between the step of solubilization of the aggregated proteins in the inclusion bodies/denaturation and the renaturation/refolding step. For these reasons, it would require further, undue experimentation of a person of ordinary skill in the art to identify chemokines which may be purified by the instant method interposing Reverse Phase Chromatography step between the step of solubilization of the aggregated proteins in the inclusion bodies/denaturation and the step of renaturation/refolding step. The specification does not provide guidance or examples other than those recited to show that the purification. Therefore a person of ordinary skill in the art would not know how to make and use the current method to purify all chemokines.

In summary, due to the excessive breadth of the claims, which read on recovery of all chemokines, the lack of guidance and examples in the, and the unpredictability inherent in the invention regarding the purification of chemokines, a person of ordinary skill in the art would require further, undue experimentation to determine the chemokines that can be purified by interposing Reverse Phase Chromatography step.

3b. Claims 1-3 and 6-8 are rejected under 35 U.S.C. 112, first paragraph, containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a process for the recovery of chemokines expressed in prokaryotic host cells by interposing Reverse Phase Chromatography step between the

step of solubilization of the aggregated proteins in the inclusion bodies/denaturation and the step of renaturation/refolding step. The claims do not require that the chemokines be of a specific structure etc.

In addition, which regions must be conserved in order to purified using the instant method is not clear. Further, there is no disclosure of other chemokines other than RANTES of SEQ ID NO: 1. Thus, the Applicants have not fully described the genus of the instant invention and thus capable of being used commensurate in scope with the claims.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a requirement that the molecule be a chemokine.

There is no identification of any chemokine other than RANTES of SEQ ID NO: 1. There is no disclosure of other chemokines. Accordingly, in the absence of sufficient distinguishing characteristics, the specification does not provide adequate written description of the claimed genus.

### ***Conclusion***

4. No claims are allowed. However, if limitation of claim 1 is incorporated into claim 5, it will be allowable.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEGATHEESAN SEHARASEYON whose telephone number is (571)272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph. D can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Application/Control Number: 10/586,141

Page 6

Art Unit: 1646

Examiner, Art Unit 1646